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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,457	02/21/2002	Anne M. Pianca	98P1021US08	3029
36802	7590	08/23/2005		
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 08/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,457

Applicant(s)

PIANCA ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5, 6, 9, 12, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain (5925073) in view of Hsu et al (6430449).

Chastain discloses the claimed invention except for a ring electrode located on a bend (and the bends located 0.15-0.7 inches from each other--claim 8). Hsu teaches that it is known to locate a ring electrode on the bend to allow the electrode to be mechanically biased into physical contact with the coronary vein and therefore provide more effective stimulation and teaches to provide bends located 8-11 mm from each other (for claim 8) to stabilize the lead in the coronary vein. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with a ring electrode

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located on the bend and the bends located 8-11 mm from each other as taught by Hsu, since such a modification would provide a heart lead with a ring electrode located on the bend to allow the electrode to be mechanically biased into physical contact with the coronary vein and therefore provide more effective stimulation and would provide a heart lead with the bends located 8-11 mm from each other to stabilize the lead in the coronary vein.

Claims 4, 11, and 14 are rejected under 35 U.S.C. 103(a) as obvious over Chastain et al. Chastain shows in figures 1, 4, and 6 the lead having non-helical bends comprising two-sides forming an angle in the range of about 45 degrees, which is in the range of 30-150 degrees. In addition, Chastain states that a guidewire is used (column 3) and therefore would require a distal opening. Finally, for claim 4, Chastain will meet the intended use recitations presented in the claim since the stylet can be moved anywhere along the bends to cant the tip toward the patient's wall (the "steerable canted end" is used in claim 2 when the stylet is partially withdrawn) and since Chastain's electrode is oriented toward a wall since the electrode is oriented by the bends.

In the alternative, Chastain discloses the claimed invention except for the bends having an angle of 30-150 degrees, a distal opening for a guidewire, and the tip electrode oriented toward the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Chastain, with the bends having an angle of 30-150 degrees, a distal opening for a guidewire, and a tip electrode oriented toward the coronary wall since it was known in the art that heart leads having an anchor use: anchor bends having an angle of 30-150 degrees to allow the lead to easily anchor in the heart and provide

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good stability to prevent movement of the lead; a distal opening in the lead to allow the lead to be accurately placed in the heart using the guidewire; and the tip electrode oriented toward the coronary wall to provide physical contact with the wall for more effective stimulation.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain et al as applied to claims 6 and 1 above.

Chastain discloses the claimed invention except for the humps being in different geometric planes. It would have been an obvious matter of design choice to one skilled in the art to modify the anchoring lead as taught by Chastain with the humps in the anchor being located in different geometric planes, since applicant has not disclosed that providing the humps in different geometric planes provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location of the humps, such as the humps being located in the same plane as taught by Chastain to anchor the lead in the coronary sinus and provide contact with the wall only along the humps.

Claims 3, 7, 8, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chastain as applied to claims 2, 6, and 1 above. For claim 8, Hsu states that the bends are located 8-11 mm from each other. In addition, for claim 7, Chastain shows in figure 1 the bends being located 4-20 cm from the end and states the length of the bends are 4-7 cm long (column 2) and therefore provide a first bend located in the range of 0.15-0.7 inches from the distal end (in the alternative, see the rejection below).

Chastain discloses the claimed invention except for the stylet having a tapered portion, the first bend located in the range of 0.15-0.7 inches from the distal end, and the lead having a textured region of ePTFE or porous material. It would have been obvious to one having ordinary

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skill in the art at the time the invention was made to modify the medical electrical lead as taught by Chastain with the stylet having a tapered portion, and the lead having a textured region of ePTFE or porous material (such as silicone rubber, polyurethane, or ceramic) since it was known in the art that medical electrical leads use a stylet with a tapered portion to allow the stylet to fit in the narrow distal end of the lead and to position the lead, and that leads have a textured region of ePTFE or porous material to allow the lead to anchor in the body.

In addition, it would have been an obvious matter of design choice to one skilled in the art to modify the medical electrical lead as taught by Chastain to include ePTFE as the textured region and the first bend being located 0.15-0.7 inches from the distal end, since applicant has not disclosed that ePTFE and the first bend being located 0.15-0.7 inches from the distal end provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any biocompatible textured material or any location of the bends, such as silicone rubber, polyurethane or ceramic for allowing the lead to anchor in the body as taught by Chastain in view of one having ordinary skill in the art for allowing the lead to anchor in the coronary sinus or such as the S-shaped or zig-zag shaped lead location of the bends as taught by Chastain to allow the lead to anchor in the coronary sinus and provide electrodes for electrical contact with the heart chambers.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

8/21/15

GRE
August 21, 2005